

PATENT

ATTORNEY DOCKET NO.: BAL-106 (K-C No. 17349)

**COMPOSITION FOR THE DETECTION OF
GASTROINTESTINAL DISORDERS**

Background of the Invention

This invention⁵ claims priority to PCT/US02/29814 which is a continuation of US 09/977,555, filed 10-15-2001.
CF 2/04

caused at least in part by bacteria. Such bacteria include those of the genus *Campylobacter*, and particularly *Helicobacter pylori*. For example, *Helicobacter pylori* can cause bacterial infections on the mucosal surface of the gastrointestinal tract, particularly on the surface of the stomach. The chronic disorders of the gastrointestinal system that can be caused by bacteria include peptic ulcers, gastritis, and the like.

Once a patient is showing symptoms of a gastrointestinal disorder, several tests can be used to diagnose the disorder, including the diagnosis of a possible bacterial infection. In the past, various tests have been proposed for the detection of *Helicobacter pylori*. One such test that has gained wide spread popularity and has provided many advancements in the early detection of gastrointestinal disorders is disclosed in U.S. Patent No. 4,748,113, which is incorporated herein by reference. In the '113 patent, the presence of *Helicobacter pylori* in a gastric sample is detected by testing for the presence of an enzyme, specifically urease, which is produced by *Helicobacter pylori* in large amounts.

Urease is known to convert urea into ammonium carbonate, which then decomposes into ammonia and carbon dioxide. Consequently, in the past, one test for detecting the presence of *Helicobacter pylori* included the steps of contacting a sample of gastric material with a composition containing urea and an indicator, namely a pH indicator that changes color when there is a rise in pH. If urease is present within the gastric material it breaks down the urea, which results in the formation of ammonia after further decomposition and causes the pH indicator to